



UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/358,474 12/19/94 KYLE

D 0311.48526

EXAMINER

JORDAN, K

ART UNIT

PAPER NUMBER

1205

DATE MAILED:

10/26/95

12M2/1026
BANNER BIRCH MCKIE & BECKETT
ELEVENTH FLOOR
1001 G STREET NW
WASHINGTON DC 20001-4597

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

- ☐ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire _____ month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☐ Claims _____ are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other _____

EXAMINER'S ACTION



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

L.T.
10-25-95

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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#7

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED:

☒ This application has been examined ☒ Responsive to communication filed on June 28, 1995 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 months from the date of this letter.
Failure to respond within the time period will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENTS ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-28, 30-33, 36-42 and 67-82 are pending in the application.
Of the above claims, _____ are withdrawn from consideration.
2. ☒ Claims 29, 34-35 and 43-66 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-28, 30-33, 36-42 and 67-82 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____ has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under 35 USC 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Art Unit: 1205

Claims 1-28, 30-33, 36-42, and 67-82 are presented for examination.

Claims 67-82 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to compositions where there is no limitation on the presence of EPA. The phrases "substantially free" or "essentially free" of EPA in claims 67 and 70 are not enabled or disclosed by the specification. See M.P.E.P. §§ 706.03(n) and 706.03(z).

Claims 7-11 and 13-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 7 and 13 are indefinite due to a lack of antecedent basis for the term "said genera". The remaining claims are indefinite to the extent that they depend on the rejected base claims.

Claims 30-33 are rejected as being of improper dependent form as they depend on a cancelled claim (claim 29).

Claims 1-17, 21-24, 30-33, 36-39, 67-74, and 77-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 20-22 of U.S. Patent No. 5,374,657. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the application are equivalent

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to or encompassed by the claims of the patent. Furthermore, claims of the application specifying the oil source are also obvious because the source does not change the chemical structure of the triglyceride or fatty acid.

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same

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person or subject to an obligation of assignment to the same person.

Claims 1-28, 30-33, 36-42, and 67-82 are rejected under 35 U.S.C. § 103 as being unpatentable over Japanese Patent Application #196,255 and PCT Application #WO89/00606 in view of Clandinin et al. and Traitler et al.

The claims appear to be drawn to processes, compositions, and nutritional supplements for enriching infant formulas or milk by adding polyunsaturated fatty acids from microbial, plant, and fish oil sources. JPA #196,255 teaches the process of adding microbial oils produced by Mortierella bacteria to supplement milk for infants (see pages 4-5 and 7-8). The microbial oils contain polyunsaturated fatty acids such as gamma-linoleic acid (GLA), arachidonic acid (ARA), and eicosapentaenoic acid (EPA) (see pages 4-5 and 7-8). PCT Application #WO89/00606 teaches the supplementation of infant and adult nutritional formulas with microbial oils containing the polyunsaturated fatty acids docosahexaenoic acid (DHA) and EPA (see pages 3-5). The microbial oils are obtained from the fungi, Pythium and from the microalgae, Nitzschia and Cryptocodium (see page 5). The claimed subject matter differs from the primary references in claiming the addition of GLA obtained from plant and fish oils. To supplement infant formulas with GLA obtained from plant and fish oils would have been obvious in view of Clandinin et al. and Traitler et al. Clandinin et al. teaches the addition of fatty

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-5-

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acids from fish oil to infant formula (see column 2, line 61-column 3, line 8, and column 6, line 8-column 7, line 17). Traitler et al. teach the addition of GLA to infant formula wherein the GLA is obtained from black current oil (see column 3, lines 21-61). The choice of various ratios for the ingredients is deemed to be nothing more than the optimization of the composition which is within the skill of the artisan. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. The remaining references listed on the enclosed PTO-1449 are cited to show the state of the art.

No claims are allowed.

A facsimile center has been established in Group 1200, room 3C10. The hours of operation are monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine is (703) 308-4556 or 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Jordan whose telephone number is (703) 308-4611.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


KIMBERLY JORDAN
PRIMARY EXAMINER
GROUP 1200

JORDAN:jd
OCTOBER 11, 1995